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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/639,859	08/16/2000	Leonard S. Girsh	5163*3	2441

23557 7590 12/02/2002

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 12/02/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/639,859

Applicant(s)

GIRSH, LEONARD S.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,15-18 and 23-95 is/are pending in the application.
- 4a) Of the above claim(s) 1,3-11,15-18,23-44 and 84-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-83 and 89-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group VI, claims 45-83 and 89-95 without traverse in Paper No. 15, filed September 19, 2002 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 47, 48, 51, 52, 58, 60, 66, 67, 69-71, 74-81 and 89-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 47, 48, 51, 52, 66, 67, 69-71, and 80 are indefinite because of the use of the term "derived from". The term "derived from" renders the claim indefinite, it is unclear how different the compound derived from cellular or tissue sources is as compared to the compound in the cellular or tissue sources. Use of the term "obtained from" is suggested. Claims 52, 66, 67, 69-71, 80 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

4. Claims 58, 71 and 73 are indefinite because of the use of the term "and/or". The term "and/or" renders the claim indefinite, it is unclear whether the limitation after "and/or" is included or not, and if included is to be read as an alternative "or" or the conjunctive "and". Use either "or" or "and" not both.

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5. Claims 58 and 60 are indefinite because of the use of the term “L-glycine”. The term “L-glycine” renders the claim indefinite, it is unclear how glycine ($\text{H}_2\text{N}-\text{CH}_2\text{COOH}$) which does not have a chiral center can have L form.

6. Claims 74-77 are indefinite because of the use of the term “any combination of (a) through (j)”. The term “any combination of (a) through (j)” renders the claim indefinite, it is not clear what combination is intended as to the number of components and the amount of each component.

7. Claims 78-79 are indefinite because of the use of the term “biochemically key components that pharmacodynamically continue bonding effects....disease tissue”. The term cited renders the claim indefinite, it is unclear what the biochemical key components are, and how these key components continue bonding effects in reorganization, regrowth and regeneration of normal tissue or disease tissue. The word “biochemically” is misspelled, use of “biochemical” is suggested.

8. Claims 80-81 are indefinite because of the use of the term “said molecular bonding forces are maximized”. The term cited renders the claim indefinite, it is unclear how the molecular bonding forces are maximized.

9. Claim 89, for example, is indefinite because of the use of the term “ratio of amino acid components in peptides, polypeptides, proteins, medicants or tissues”. The term “ratio of amino acid components in peptides, polypeptides, proteins, medicants or tissues” renders the claim indefinite, it is unclear what are the ratios of the amino acid components in peptides, polypeptides, proteins, medicants or tissues because the peptides, polypeptides, proteins, medicants or tissues are not identified. See also claims 90-95.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 45-54 and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by Garson *et al.* (U. S. Patent 5,753,211).

Garson *et al.* teach a composition for treating nails comprising collagen, cystine, phospholipids, vitamins and other active agents (column 3, lines 17-26; claims 45, 53, 54 and 74), and it is known that collagen, cystine, phospholipids and vitamins can be synthetically produced or isolated from cellular or tissue sources (claims 46-52).

11. Claims 55-57, 59, 61-65, 68, 72, 73, 82 and 83 are rejected because the claim depends from a rejected claim.

Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

November 29, 2002

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600